IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Miragaya, et al.	Examiner:	Macauley, Sheridan R
Serial No:	10/540,296	Group Art Unit:	1651
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Filed:	January 20, 2006	Dated:	November 23, 2010
For:	FORMULATIONS FOR THE RECTAL ADMINISTRATION OF THROMBOLYTICALLY-ACTIVE AGENTS		

Commissioner for Patents
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(Printed Name)

Signature: /Anne C. Arlauskas/

DECLARATION UNDER 37 C.F.R. §1.132

I, Ana Aguilera Barreto, do hereby declare as follows:

1. I am a co-inventor of U.S. patent application serial number 10/540,296.

2. I am part of the team that designed and conducted clinical trials (phase II and phase III) to test the efficacy of the methods claimed in the '296 application. See Exhibits B and C attached hereto.

3. In the phase II study, three (3) groups of patients suffering from hemorrhoids were observed. Group I was given a placebo. Group II was given a placebo with sodium salicylate. Group III was given recombinant streptokinase plus salicylate. See Exhibit B.

4. The phase II study observed patients after 5 days of treatment. In Table 1, Group III shows 52.4% of patients had a reduction of more than 90% of the initial size of the lesion by day 5. Groups I and II had a significantly lower response.

5. Table 2 of the phase II study shows the percent of patients that had a decrease of more than 70% in size of the initial lesions and elimination of pain and edema ("total response") on day 5. Group III showed 66.7% of patients had a total response. Groups I and II showed 36.8% and 35.0% total response, respectively.

6. The data collected in Exhibit B clearly shows that the active ingredient, streptokinase, was the cause of the effective treatment of the hemorrhoids.

7. The phase III study compared treatment of patients suffering from hemorrhoid disease with Preparation H® and streptokinase. At the various treatment milestones, it is shown that patients treated with streptokinase showed a significant increase in treatment of their hemorrhoids over patients treated with Preparation H®. See Exhibit C.

8. Furthermore, in the application as filed, the compositions tested and compared in Example 5 and Table 2 consist essentially of streptokinase (SK) or tissue-type plasminogen activator (t-PA).

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true. Further, I hereby declare that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States code, and that such wilful false statements may jeopardize the validity of the application of any patent issued thereon.

Respectfully submitted,

Dated: 23.11.2010

Signed: _____
Ana Aguilera Barreto